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December 19, 2005

The Honorable Kent A. Jordan  
United States District Judge  
J. Caleb Boggs Federal Building  
844 North King Street, Room 6325  
Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re: In re '318 Patent Infringement Litigation, Civil Action No. 05-356-KAJ

Dear Judge Jordan:

This letter responds to Defendants' December 16, 2005 letter to the Court submitted in advance of the telephone conference with the Court scheduled for 10:00 a.m. on Tuesday, December 20, 2005.

Defendants seek to revise the schedule set by the Court on October 21, 2005. They have submitted a proposed schedule that would truncate the original schedule by eight months, moving the trial from October 9, 2007 to February 19, 2007, and essentially cut the time for both fact and expert discovery in half. In the spirit of cooperation, Plaintiffs are willing to expedite certain deadlines and have submitted a counter-proposal that trims one and a half months from the current schedule. (Ex. A.) However, Plaintiffs believe Defendants' drastic proposed schedule revisions are unfair and would prejudice their rights to adequate fact and expert discovery, and are not warranted by developments in the litigation, including Defendants' failure to cooperate in discovery matters.

### Defendants' Infringement Stipulation Does Not Significantly Reduce the Need for Discovery

Defendants cite their stipulation to infringement and to the use of common experts as the purported justification for such a dramatic revision to the trial schedule. But the focus of this case has never been infringement. To the contrary, the key issues in this case have always centered on the validity of the '318 patent, as shown by Defendants' Paragraph IV notices, which allege only invalidity, not non-infringement.

Elimination of infringement from the case therefore will not significantly reduce the need for discovery. At best, it will eliminate one deposition per defendant. More realistically, it will merely trim time from depositions that will still need to move forward. As to Defendants' concession to use common experts, Plaintiffs' proposed schedule adequately reflects this concession by advancing the commencement of expert discovery by one month.

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Need for Third-Party Discovery

Moreover, as was discussed at the first hearing, this case involves significant third-party discovery. The '318 patent claims the drug substance galantamine as a treatment for Alzheimer's disease, and the defendants assert that those claims are obvious. Plaintiffs are entitled to meet this assertion with evidence of skepticism concerning the likely success of the patented invention – evidence the Federal Circuit has termed "relevant and persuasive" evidence of non-obviousness. *E.g., Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998). Here, considerable evidence of industry skepticism resides with third parties, including several drug companies that rejected licensing efforts by the inventor, Dr. Bonnie Davis, expressly because they were skeptical that the claimed invention would work. Wyeth, for instance, evaluated Dr. Davis' invention but declined to license it specifically because, in Wyeth's words, "[t]here is still skepticism regarding the success of cholinesterase inhibitors [which includes galantamine] in the treatment of senile dementia." (Ex. B.) Boehringer Ingelheim similarly rejected galantamine because it believed at the time that the drug "does not have the biochemical and pharmacological profile which we consider essential for its potential use in the treatment of Alzheimer's disease." (Ex. C.) And these are just two examples.

Third-party discovery takes time. Plaintiffs have issued a subpoena to Wyeth to obtain discovery related to this issue. Boehringer, however, is located abroad, and Plaintiffs may need to invoke the formal channels of foreign discovery – a complicated process which could take between 6 and 14 months. Plaintiffs are in the process of pursuing that discovery.

Defendants' proposed cut-off for fact discovery does not even come close to allowing Plaintiffs adequate time to obtain such relevant third-party discovery. Approving Defendants' extreme proposed modification to the fact discovery cut-off would impact Plaintiffs' substantive rights to defend the validity of the '318 patent.

Uncooperativeness of Defendants

Defendants have been consistently uncooperative in discovery to date, exhibiting behavior which undermines their request for an expedited schedule. Their foot-dragging demonstrates why fact discovery realistically cannot be completed by April without severely compromising the parties' ability to litigate the merits.

For over four months, Plaintiffs have been seeking discoverable materials from Defendants, but important materials have not yet been produced. Like Wyeth and Boehringer, defendant Mylan too declined to license the patent in 1990, a decision that Plaintiffs believe was similarly driven by skepticism about the likely success of invention. Plaintiffs have repeatedly asked Mylan – and the other defendants – to produce all documents related to their consideration of licensing the '318 patent, and any other documents concerning "evaluation, analysis, or discussion" of the patented invention. Defendants have so far failed to produce any documents in response to this request – indeed the only documents produced so far in this litigation

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concerning Mylan's contemporaneous analysis of the patented invention have come from Plaintiffs' files, not Mylan's. Most recently, Mylan wrote to Plaintiffs stating simply that it was still looking for these documents – months after the documents were requested. While Plaintiffs recognize that document production and fact discovery take time, Defendants' own delay in producing documents further demonstrates the unfairness of their attempt to drastically curtail discovery in this case.

At the October 12, 2005 conference, the Court predicated its willingness to entertain a shortened schedule on the cooperation of the parties in discovery. The Court noted: "If you folks are successful in cooperating discovery in a manner that brings this thing in sooner, that's great.

... If everybody comes to me at our first status conference and says 'Judge, cooperation amongst the defendants is excellent. Cooperation between the sides is productive. We think we can bring this in sooner.' I will move that trial date up further, if it's at all possible." (10/12/05 Tr. at 25, Ex. D). The Court should not excuse Defendants' uncooperativeness by advancing the schedule, particularly in light of the prejudice that would be inflicted by Plaintiffs.

There are other problems with Defendants' proposed schedule. For example, the Court's current Scheduling Order (¶ 2) sets the cut-off for joinder of parties and amendment of the pleadings six months before the close of fact discovery. Defendants' new proposed order would shorten the deadline from six to two months before the close of fact discovery. This Court, in the first hearing, already rejected Defendants' proposal to shorten the time for discovery following amendment of the pleadings, and Defendants provide no justification for the Court to reconsider its judgment. Indeed, such a short timeframe would unfairly curtail Plaintiffs' opportunity to take discovery on any new claims or defenses asserted by Defendants.

In closing, Plaintiffs are willing to concede to some scheduling changes, as reflected by their counter-proposal for schedule revisions. However, Plaintiffs respectfully oppose sacrificing relevant and important discovery in order to bring the case to trial sooner, particularly when Defendants have proven uncooperative in discovery matters. Moreover, Plaintiffs do not endorse any schedule which is unrealistic, and which will inevitably require further revisions and extensions by the Court. Adopting a significantly shortened schedule would only place the parties and the Court in this position.

We look forward to speaking with Your Honor by telephone tomorrow morning about these issues.

Respectfully,



Steven J. Balick

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